Table 1. Level 1 Component and Composition Changes for Immediate Release Oral Solid Dosage Forms

Excipient	Percent Excipient (w/w) Out of Total Target Dosage Form Weight
Filler	+/- 5%
Disintegrant starch other	 +/- 3% +/- 1%
Binder	+/- 0.5%
Lubricant calcium or magnesium stearate other	 +/- 0.25% +/- 1%
Glidant talc other	 +/- 1% +/- 0.1%
Film coat	+/- 1%

Table 2. Level 2 Component and Composition Changes for Immediate Release Oral Solid Dosage Forms

Excipient	Percent Excipient (w/w) Out of Total Target Dosage Form Weight
Filler	+/- 10%
Disintegrant starch other	 +/- 6% +/- 2%
Binder	+/- 1%
Lubricant calcium or magnesium stearate other	 +/- 0.5% +/- 2%
Glidant talc other	 +/- 2% +/- 0.2%
Film coat	+/- 2%

Figure 1

Table 3. Level 3 Component and Composition Changes for Immediate Release Oral Solid Dosage Forms

Excipient	Percent Excipient (w/w) Out of Total Target Dosage Form Weight
Filler	Greater than +/- 10%
Disintegrant starch other	 Greater than +/- 6% Greater than +/- 2%
Binder	Greater than +/- 1%
Lubricant calcium or magnesium stearate other	 Greater than +/- 0.5% Greater than +/- 2%
Glidant talc other	 Greater than +/- 2% Greater than +/- 0.2%
Film coat	Greater than +/- 2%

Table 4. Level 1 Component and Composition Changes for Modified Release Oral Solid Dosage Forms (nonrelease controlling excipient)

Excipient	Percent Excipient (w/w) Out of Total Target Dosage Form Weight
Filler	+/- 5%
Disintegrant starch other	 +/- 3% +/- 1%
Binder	+/- 0.5%
Lubricant calcium or magnesium stearate other	 +/- 0.25% +/- 1%
Glidant talc other	 +/- 1% +/- 0.1%
Film coat	+/- 1%

Figure 2

Table 5. Level 2 Component and Composition Changes for Modified Release Oral Solid Dosage Forms (nonrelease controlling excipient)

Excipient	Percent Excipient (w/w) Out of Total Target Dosage Form Weight
Filler	+/- 10%
Disintegrant starch other	 +/- 6% +/- 2%
Binder	+/- 1%
Lubricant calcium or magnesium stearate other	 +/- 0.5% +/- 2%
Glidant talc other	 +/- 2% +/- 0.2%
Film coat	+/- 2%

Table 6. Level 3 Component and Composition Changes for Modified Release Oral Solid Dosage Forms (nonrelease controlling excipient)

Excipient	Percent Excipient (w/w) Out of Total Target Dosage Form Weight
Filler	Greater than +/- 10%
Disintegrant starch other	 Greater than +/- 6% Greater than +/- 2%
Binder	Greater than +/- 1%
Lubricant calcium or magnesium stearate other	 Greater than +/- 0.5% Greater than +/- 2%
Glidant talc other	 Greater than +/- 2% Greater than +/- 0.2%
Film coat	Greater than +/- 2%

Figure 3

Table 7. Level 1 Component and Composition Changes for Modified Release Oral Solid Dosage Forms (release controlling excipient)

Excipient	Percent Excipient (w/w) Out of Total Release Controlling Excipient Content in the Modified Release Solid Oral Dosage Form
Any release controlling excipient(s)	+/- 5%

Table 8. Level 2 Component and Composition Changes for Modified Release Oral Solid Dosage Forms (release controlling excipient)

Excipient	Percent Excipient (w/w) Out of Total Release Controlling Excipient Content in the Modified Release Solid Oral Dosage Form
Any release controlling excipient(s)	+/- 10%

Table 9. Level 3 Component and Composition Changes for Modified Release Oral Solid Dosage Forms (release controlling excipient)

Excipient	Percent Excipient (w/w) Out of Total Release Controlling Excipient Content in the Modified Release Solid Oral Dosage Form
Any release controlling excipient(s)	Greater than +/- 10%

Figure 4

Table 10. Schematic of use within the commercial pipeline

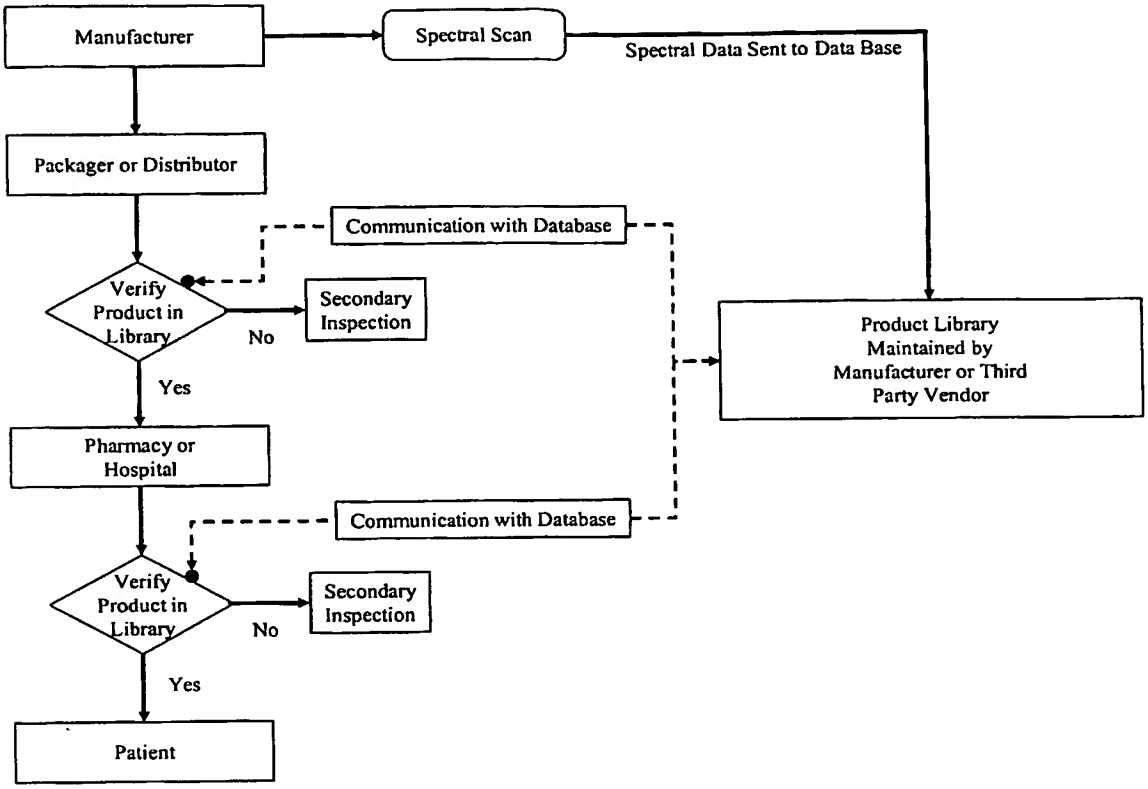

Figure 5

Table 11. Composition of Aspirin Formulations

Component	Formulation A1 (mg/tab)	Formulation A2 (mg/tab)	Formulation A3 (mg/tab)
Aspirin	325	325	325
Microcrystalline cellulose	73	83	63
Magnesium stearate	2	2	2
TOTAL WEIGHT	400	410	390

Table 12. Composition of Prednisone Formulations

Component	Formulation B1 (mg/tab)	Formulation B2 (mg/tab)	Formulation B3 (mg/tab)
Prednisone	5	5	5
Microcrystalline cellulose	94.5	94.5	94.5
Magnesium stearate	0.5	0.75	0.25
TOTAL WEIGHT	100	100.25	99.75

Table 13. Composition of Indomethacin Formulations

Component	Formulation C1 (mg/tab)	Formulation C2 (mg/tab)	Formulation C3 (mg/tab)
Indomethacin	25	25	25
Microcrystalline cellulose	71.5	74	69
Croscarmellose sodium	3	2	4
Magnesium stearate	0.5	0.5	0.5
TOTAL WEIGHT	100	101.5	98.5

Table 14. Compositions of Acyclovir Formulations

Component	Formulation D1 (mg/tab)	Formulation D2 (mg/tab)	Formulation D3 (mg/tab)
Acyclovir	200	200	200
Microcrystalline cellulose	113.26	120.26	106.26
Starch	35	27.99	41.99
Magnesium stearate	1.75	1.75	1.75
TOTAL WEIGHT	350	350	350

Figure 6

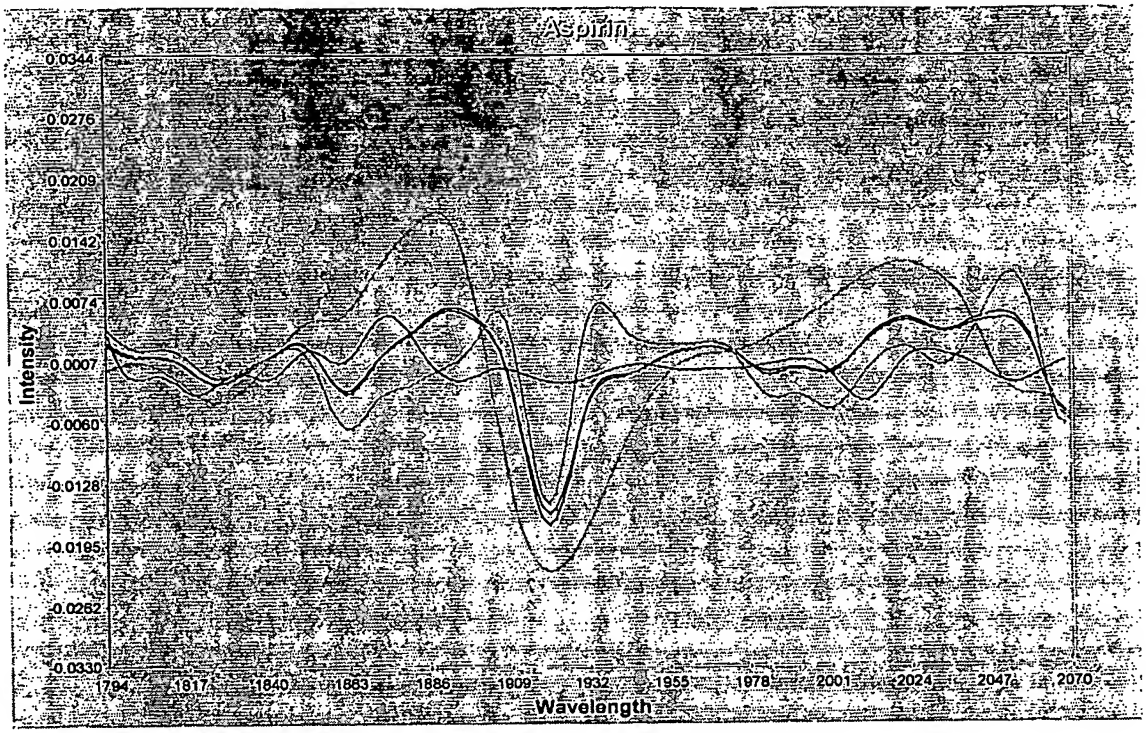

Table 15. 2nd Derivative of Absorbance vs. Wavelength: Aspirin Formulations

Figure 7

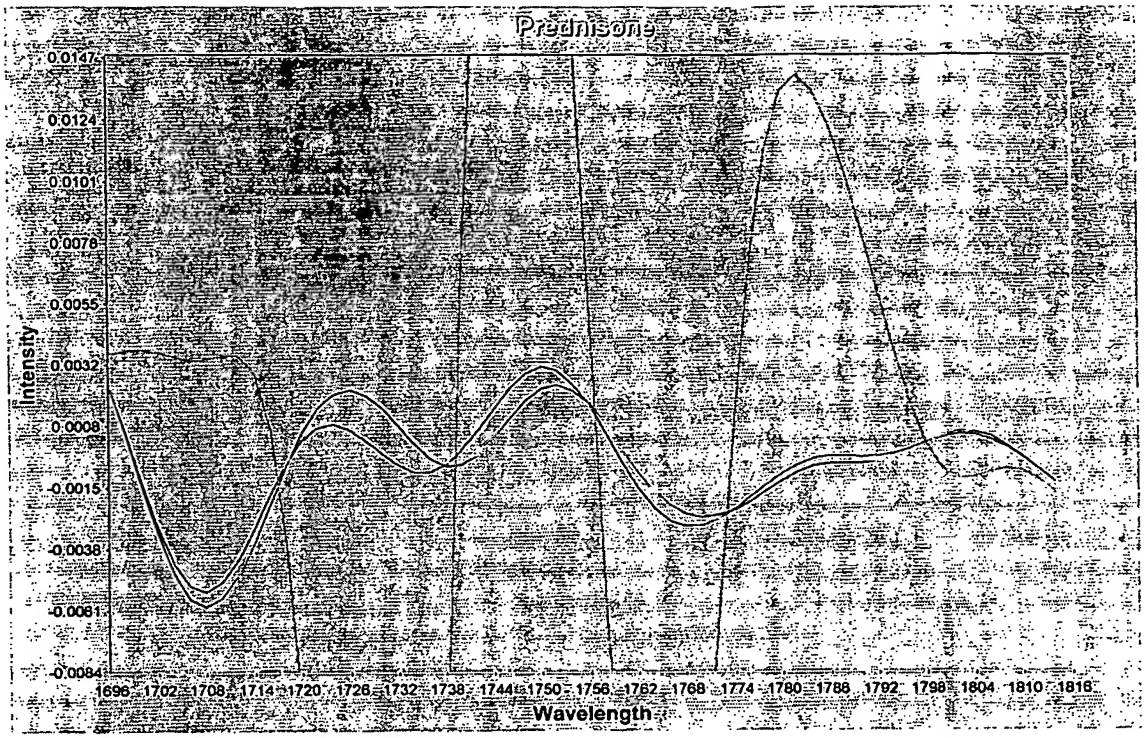

Table 16. 2nd Derivative of Absorbance vs. Wavelength: Prednisone Formulations

Figure 8

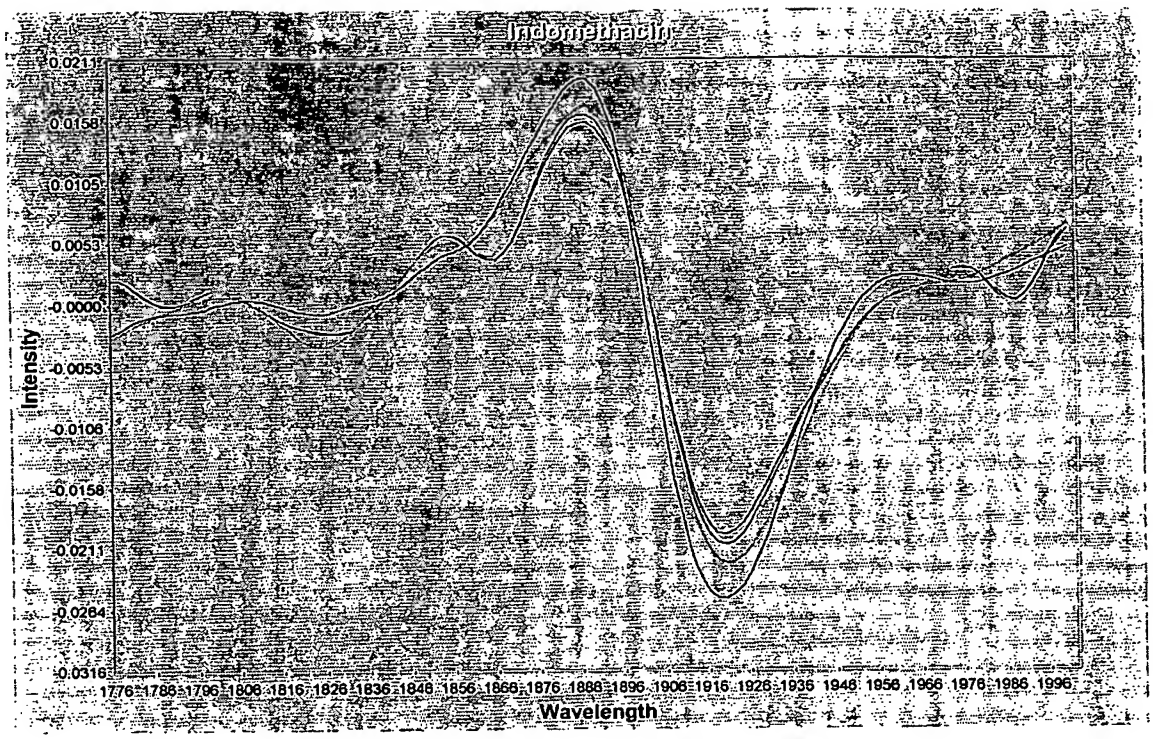

Table 17. 2nd Derivative of Absorbance vs. Wavelength: Indomethacin Formulations

Figure 9

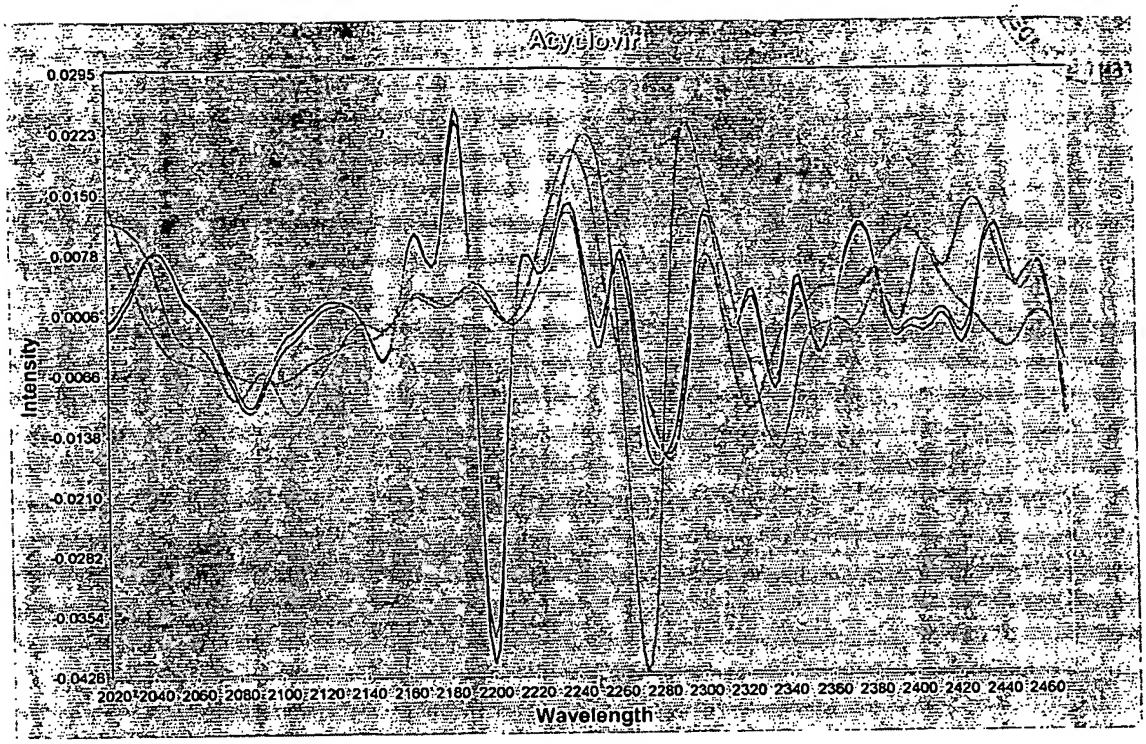

Table 18. 2nd Derivative of Absorbance vs. Wavelength: Acyclovir Formulations

Figure 10